

Application No. 10/575,691
October 27, 2010
Reply to Office Action of August 27, 2010

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. (Original) An antibiotic composition comprising coated micropellets and optionally one or more excipients, wherein said coated micropellets comprise
 - (i) a core comprising at least one antibiotic;
 - (ii) an inner coating comprising at least one cellulose polymer which is not an enteric coating polymer; and
 - (iii) an outer coating comprising at least one enteric coating polymer, wherein said coated micropellets have a mean particle size of about 100 μm to about 650 μm .
2. (Original) The composition according to Claim 1, wherein the coated micropellets have a mean particle size of about 200 μm to about 500 μm .
3. (Original) The composition according to Claim 1, wherein at least about 90% of the coated micropellets have a particle size of about 100 μm to about 650 μm .
4. (Original) The composition according to Claim 1, wherein the cellulose polymer is selected from the group consisting of hydroxypropylmethyl cellulose, hydroxypropyl cellulose, methyl cellulose, ethyl cellulose, carboxymethylethyl cellulose, sodium carboxymethyl cellulose, ethylcarboxyethyl cellulose, and combinations thereof.
5. (Original) The composition according to Claim 1, wherein the inner coating additionally comprises at least one plasticizer.
6. (Original) The composition according to Claim 5, wherein the plasticizer is selected from the group consisting of acetyl-triethyl citrate, acetyl tributyl-, tributyl-, triethyl-citrate, glycerol diacetate, glycerol triacetate, acetylated monoglycerides, castor oil, dibutyl-phthalate, diamyl- phthalate, diethyl-phthalate, dimethyl-phthalate, dipropyl-phthalate, di-

(2-methoxy- or 2- ethoxyethyl)-phthalate, ethylphthalyl glycolate, butylphthalylethyl glycolate, butylglycolate, propylene glycol, polyethylene glycol, diethyladipate, di- (2-methoxy- or 2-ethoxyethyl)- adipate, benzophenone, diethyl- and diburylsebacate, dibutylsuccinate, dibutyltartrate, diethylene glycol dipropionate, ethyleneglycol diacetate, ethyleneglycol dibutyrate, ethyleneglycol dipropionate, tributyl phosphate, tributyrin, polyethylene glycol sorbitan monooleate, sorbitan monooleate, and combinations thereof.

7. (Original) The composition according to Claim 6, wherein the plasticizer is polyethylene glycol.
8. (Original) The composition according to Claim 1, wherein the enteric coating polymer is selected from the group consisting of cross-linked polyvinyl pyrrolidone; non-cross linked polyvinylpyrrolidone; hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose acetate succinate, cellulose acetate succinate; cellulose acetate phthalate, hydroxypropylmethyl cellulose acetate succinate, cellulose acetate trimellitate, hydroxypropyl methyl cellulose phthalate; hydroxypropyl methyl cellulose acetate succinate; starch acetate phthalate; polyvinyl acetate phthalate; carboxymethyl cellulose; methyl cellulose phthalate; methyl cellulose succinate; methyl cellulose phthalate succinate; methyl cellulose phthalic acid half ester; ethyl cellulose succinate; carboxymethylamide; potassium methacrylatedivinylbenzene copolymer; polyvinylalcohols; polyoxyethyleneglycols; polyethylene glycol; sodium alginate; galactomannone; carboxypolymethylene; sodium carboxymethyl starch; copolymers of acrylic acid and/or methacrylic acid with at least one monomer selected from the group consisting of methyl methacrylate, ethyl methacrylate, ethyl acrylate, butyl methacrylate, hexyl methacrylate, decyl methacrylate, lauryl methacrylate, phenyl methacrylate, methyl acrylate, isopropyl acrylate, isobutyl acrylate, and octadecyl acrylate; polyvinyl acetate; fats; oils; waxes; fatty alcohols; shellac; gluten; ethylacrylate-maleic acid anhydride copolymer; maleic acid anhydride-vinyl methyl ether copolymer; styrol-maleic acid copolymer; 2-ethyl-hexyl-acrylate maleic acid anhydride; crotonic acid-vinyl acetate copolymer; glutaminic acid/glutamic acid ester copolymer; carboxymethylcellulose glycerol monoctanoate; polyarginine; poly (ethylene); poly (propylene); poly (ethylene

oxide); poly (ethylene terephthalate); poly (vinyl isobutyl ether); poly (vinyl chloride); polyurethane, and combinations thereof.

9. (Original) The composition according to Claim 8, wherein the enteric coating polymer is selected from the group consisting of a copolymer of methacrylic acid and methyl methacrylate, and a copolymer of methacrylic acid and ethyl acrylate.

10. (Original) The composition according to Claim 1, wherein the outer coating additionally comprises at least one plasticizer.

11. (Original) The composition according to Claim 10, wherein the plasticizer is tricetyl citrate and glycerol monostearate.

12. (Original) The composition according to Claim 1, wherein the antibiotic is clarithromycin.

13. (Currently Amended) An oral suspension comprising (a) an antibiotic composition which comprises coated micropellets and optionally one or more excipients, (b) additional excipients, and (c) a liquid medium solvent, wherein said coated micropellets comprise
(i) a core comprising at least one antibiotic;
(ii) an inner coating comprising at least one cellulose polymer which is not an enteric coating polymer; and
(iii) an outer coating comprising at least one enteric coating polymer, wherein said coated micropellets have a mean particle size of about 100 μm to about 650 μm .

14. (Currently Amended) The oral suspension according to Claim 13, wherein the liquid medium solvent is an aqueous medium solvent.

15. (Currently Amended) A method for preparing an antibiotic composition comprising coated micropellets and optionally one or more excipients, said method comprising
(A) providing a core material containing mixing at least one antibiotic, and optionally, one or more excipients, to form a premix;
(B) adding a solvent, and optionally one or more excipients, to the core material of

premix formed in Step (A) to provide a mixture and granulating the mixture in the presence of an impeller set at least at 50 rpm, to form a wet granulation;

(C) drying the wet granulation to provide dried granules, and optionally milling and screening the dried granules to form micropellets; and

(D) coating the micropellets with an inner coating comprising at least one cellulose polymer which is not an enteric coating polymer; and

(E) coating the micropellets from Step (D) with an outer coating comprising at least one enteric coating polymer to form coated micropellets, wherein said coated micropellets have a mean particle size of about 100 μ m to about 650 μ m.

16. (Original) The method according to Claim 15, wherein the granulation is additionally conducted in the presence of a chopper.

17. (Original) The method according to Claim 16, wherein the chopper is set at least at 1000 rpm.

18. (New) The method according to Claim 15, wherein the core material of Step (A) is provided by mixing the at least one antibiotic with at least one or more excipients to form the core material as a premix, and wherein the solvent added in Step (B) is added, optionally with one or more excipients, to the premix to provide the mixture for granulation.

19. (New) The method of Claim 15, further comprising mixing the coated micropellets with an aqueous medium to form a suspension including at least the coated microspheres, wherein the suspension may be taken orally by a subject in need thereof.